UNITED STATES DISTRICT COURT
DISTRICT OF NORTHERN NEW YORK

Susan Rosen,

Plaintiff,

v.

St. Jude Medical, Inc., and Pacesetter, Inc.,

Defendants.

1:13-CV-1159 [LEK/CFH]

COMPLAINT

JURY TRIAL DEMANDED

I. INTRODUCTION

1. Plaintiff brings this Complaint against St. Jude Medical, Inc., and Pacesetter, Inc. (collectively referred to as "St. Jude" or "Defendants") for injuries caused by manufacturing defects in the St. Jude Riata and Riata ST Leads (hereinafter referred to as "Riata Leads" or "Leads"). Plaintiff alleges that she was implanted with a defective Riata Lead and suffered injury.

2. St. Jude manufactures a variety of medical devices to treat heart conditions including implantable cardiac defibrillators ("ICDs"). Wires called Leads, are attached to the ICD, then inserted through a major vein and attached directly to the muscle on the inside of the heart, thereby connecting the ICD to the heart. Electrodes that sense the heart's rhythm are built into the lead wires and positioned in the heart, where they monitor the heartbeat and correct any irregular rhythms.

3. St. Jude Medical introduced its Riata Leads into the U.S. Market beginning

in 2002.

4. The Food and Drug Administration (FDA) issued a Class I Recall for the following Riata Lead model numbers:

Riata (8Fr): 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592; and Riata (7Fr): 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042 (collectively "Riata Leads").

II. PARTIES

A. Plaintiff

5. Plaintiff is a citizen and resident of the State of New York.

6. Plaintiff was implanted with a Riata Lead in August of 2004. In September 2012, Plaintiff first learned from her physician that her Riata lead was failing. On October 8, 2012, Plaintiff underwent invasive surgery to remove and replace the defective Riata Lead.

7. As a result of the defect in her Riata lead, Plaintiff has been injured and will continue to suffer physical, emotional, economic and other damage.

B. Defendants

8. Defendant St. Jude Medical, Inc. is a Minnesota Corporation that is headquartered in St. Paul, Minnesota at One St. Jude Medical Drive, St. Paul, Minnesota, 55117.

9. Defendant St. Jude Medical manufactures medical devices that are sold in more than 100 countries around the world.

10. Defendant Pacesetter, Inc. ("Pacesetter") is a Delaware corporation with its principle place of business at 15900 Valley View Court, in Sylmar, California. Pacesetter, doing business as St. Jude Medical Cardiac Rhythm Management Division,

develops, manufactures, and distributes cardiovascular and implantable neurostimulation medical devices, including the Riata and Riata ST leads at issue here. Pacesetter operates as a wholly owned subsidiary of St. Jude Medical, Inc.

11. At all relevant times, each of the Defendants and their directors and officers acted within the scope of their authority and on behalf of each other Defendant. During the relevant times, Defendants possessed a unity of interest between themselves and St. Jude Medical exercised control over its subsidiaries and affiliates. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiff for Plaintiff's damages.

III. JURISDICTION AND VENUE

12. The Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. § 1332 insofar as the parties are citizens of different states and the amount in controversy in this matter exceeds Seventy-Five Thousand Dollars ($75,000), exclusive of interest and costs.

13. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391 (a)(2) because Defendants regularly solicited and engaged in business and other persistent courses of conduct and derived substantial revenues from goods used in the State of New York.

IV. FACTUAL ALLEGATIONS

14. On December 15, 2010, St. Jude Medical published a "Dear Doctor" letter regarding its Riata Leads. In the 2010 letter, St. Jude indicated that issues with defects in the insulation have been identified in the Riata Lead Models 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592, 7000, 7001, 7002, 7010, 7011, 7040, 7041, and 7042.

15. Specifically, St. Jude states that "the Riata and Riata ST Family of Silicone Leads have exhibited an insulation abrasion rate of 0.47% over nine years of use." Additionally, St. Jude noted that the silicone used on these leads was "vulnerable to abrasion."

16. In the 2010 Dear Doctor Letter, St. Jude indicated that Lead insulation abrasion had been associated with:

a) Oversensing (leading to inhibition of pacing or inappropriate high voltage therapy);

b) Undersensing;

c) Loss of capture;

d) Changes in pacing and/or high voltage lead impedances; and

e) Inability to deliver high voltage therapy.

17. Despite the dangers associated with these leads, St. Jude did not initiate a voluntary recall of the leads at that time. Rather, St. Jude simply noted that it was "phasing-out" all Riata Lead models by the end of 2010.

18. On November 28, 2011, St. Jude Medical published a second Dear Doctor letter relating to the same set of Riata Lead Models as the 2010 Dear Doctor letter.

19. The November 28, 2011 Letter updated the previously published failure rates for the Riata Leads, indicating that it had increased to 0.63% from its 2010 rate of 0.47%. Again, despite the dangers associated with these leads, St. Jude did not initiate a voluntary recall.

20. On December 21, 2011, the FDA reclassified St. Jude's Dear Doctor advisories to a Class I Recall.

21. A Class I Recall is the most serious level of recall and is defined as: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

22. Specifically, the FDA indicated that the reason for the recall was that "failures associated with lead insulation abrasion on the St. Jude Medical Riata and Riata ST Silicone Endocardial Defibrillation Leads may cause the conductors to become externalized. If this occurs, this product may cause serious adverse health causes, including death."

V. CAUSES OF ACTION

A. Negligence in Manufacturing

23. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

24. Defendants have a duty to manufacture the Riata Leads consistent with the conditions of approval. Defendants breached this duty.

25. As a direct and proximate result of St. Jude's failure to properly manufacture the Riata Leads, Plaintiff has sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses, and other damages for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

B. NEGLIGENCE PER SE

26. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

27. Federal Regulations impose standards of care on St. Jude Medical related to

the manufacture, marketing, and sale of the Riata Leads.

28. Plaintiff alleges the Federal Regulations define the standard of care, and thus, St. Jude's duties are contained in, but not limited to, the following: 21 CFR 803.10; 21 CFR 803.50; 21 CFR 803.52; 21 CFR 803.53; 21 CFR 803.56; 21 CFR 806; 21 CFR 814.1; 21 CFR 814.3; 21 CFR 814.9; 21 CFR 814.20; 21 CFR 814.37; 21 CFR 814.39; 21 CFR 814.80; 21 CFR 814.82; 21 CFR 814.84; 21 CFR 820.5; 21 CFR 820.20; 21 CFR 820.22; 21 CFR 820.25; 21 CFR 820.70.

29. Plaintiff is within the class of persons the statutes and regulations protect and Plaintiff's injuries are the type of harm these statutes and regulations are to prevent.

30. Upon information and belief the Conditions of Approval for the Riata Leads issued by the FDA incorporate these statutes and regulations. Failure to comply with the Conditions of Approval invalidates the approval order. *See* 21 CFR 814.82(c). St. Jude failed to comply with the Conditions of Approval and Federal Regulations.

31. As a direct and proximate result of St. Jude's failure to comply with the FDA and conditions of approval for manufacturing the Riata Leads, Plaintiff has sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which she is entitled to compensatory and other damages and in an amount to be proven at trial.

C. NEGLIGENCE RES IPSA LOQUITUR

32. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

33. The manufacturing defects found in the Riata Leads can only occur while the devices are under the control of Defendant.

34. Plaintiff's injury was of a kind that, in the ordinary course of events, would not have happened if Defendant had manufactured the Riata Leads consistent with the FDA and Conditions for Approval.

35. Defendants were responsible for the manufacturing defect that was the direct cause of Plaintiff's injury.

36. The manufacturing defect that caused the injury was not due to the actions of Plaintiff or any third person.

37. As a direct and proximate result of Defendants' negligence, Plaintiff was injured as described herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

A. Economic and non-economic damages in an amount as provided by law and to be supported by the evidence at trial;

B. For compensatory damages according to proof;

C. For declaratory judgment that Defendants are liable to Plaintiff for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs, and losses caused by Defendants' wrongdoing;

D. For an award of attorneys' fees and costs;

E. For prejudgment interest and the costs of suit; and

F. For such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all claims in this action.

Dated: September 18, 2013

BERGER & KERNAN, P.C.

Joseph C. Berger, Esq.
10 Maxwell Drive, Suite 101
Clifton Park, New York 12065
Phone: (518) 982-1470
Fax: (518) 982-5037
jcberger@bergerkernan.com
Attorneys for Plaintiff

VERIFICATION

STATE OF NEW YORK)
) ss.:
COUNTY OF SARATOGA)

SUSAN ROSEN, being duly sworn, deposes and says:

I have read the foregoing Complaint and know the contents thereof; that the same is true to his knowledge except as to those matters therein alleged upon information and belief, and as to those matters, I believe them to be true.

Susan Rosen
SUSAN ROSEN

Sworn to before me this
18TH day of September, 2013.

Joseph C. Berger
Notary Public – State of New YorkNotary Public – State of New York

JOSEPH C. BERGER
Notary Public, State of New York
Qualified in Saratoga County
No. 02BE4791113
Commission Expires April 30, 2015